DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 99N–1309]

Obstetrical and Gynecological Devices; Classification of Female Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the preamendments female condom intended for contraceptive and prophylactic purposes. Under this rule, the preamendments female condom is being classified into class III (premarket approval). This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the FDA Modernization Act of 1997.

DATES: This rule is effective [*insert date 30 days after date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In a proposal published in the **Federal Register** of June 10, 1999 (64 FR 31164) (hereinafter referred to as the June 10, 1999, proposal), FDA solicited comments regarding the proposed classification of female condoms. The June 10, 1999, proposal provided the regulatory history of female condoms, as well as the recommendation of the Obstetrical and Gynecological Device

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Classification Panel (the Panel) that this particular device be classified into class III. Specifically, the Panel recommended that this device be classified into class III because no published laboratory or clinical study data could be found that demonstrate its safety and effectiveness. Also, the Panel believed that general controls and special controls would not provide reasonable assurance of the safety and effectiveness of the device and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. FDA agreed with the Panel's recommended classification.

The Panel also recommended that the device be identified as an intravaginal pouch because it is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. FDA proposed to change the name of the generic type of the device to female condom.

The 90-day comment period ended September 8, 1999, and FDA stated that upon consideration of public comment it would issue a final rule classifying this device. FDA received one comment endorsing the June 10, 1999, proposal.

II. Conclusion

FDA has concluded that the female condom be classified into class III because general controls and special controls do not provide reasonable assurance of the safety and effectiveness of the device, and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. FDA has further concluded that the generic type of this device be identified as ''female condom.'' FDA intends to issue a call for premarket approval applications (PMA's) for these devices.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the rule under Executive Order 12866, Executive Order 13132, the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA believes that there is no interest at this time in marketing the device to be classified by this rule. FDA is taking this action because it has determined that premarket approval is necessary to provide reasonable assurance of the safety

and effectiveness of the device, if there is any interest in marketing one in the future. Without this rule (and a subsequent requirement for PMA's), a person could market a device by claiming substantial equivalence to the Gee Bee Ring. All premarket submissions for ''female condom'' type devices that FDA has received to date have been for devices that have been found to be not substantially equivalent to the Gee Bee Ring and, therefore, those devices are not preamendments devices and are not to be classified by this rule. Under section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), a rule requiring PMA's for this device could not take effect any sooner than 30 months after the effective date of a final rule classifying the device or 90 days after publication of the final rule requiring the PMA's, whichever is later.

The agency therefore certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this rule requires no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

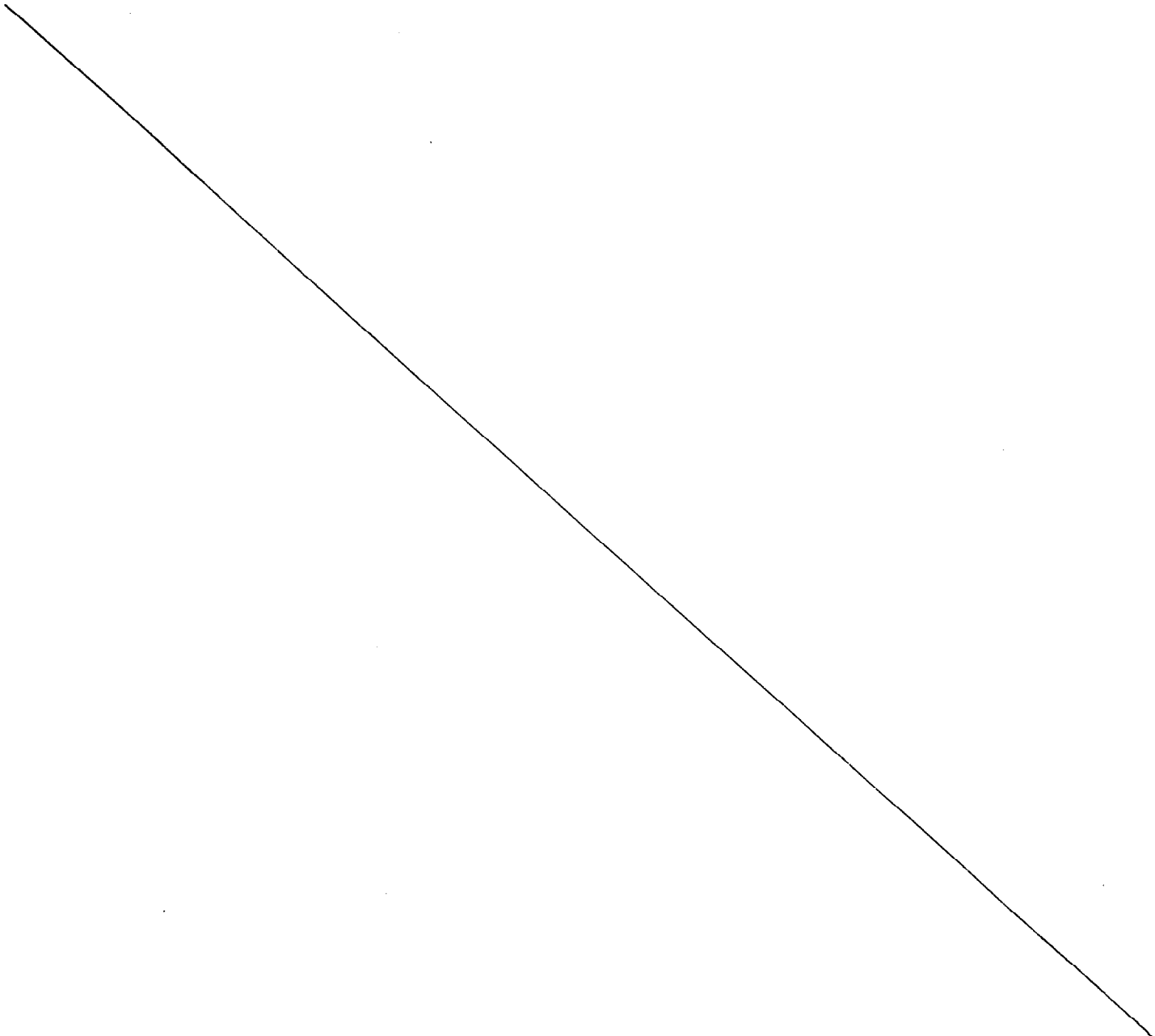
2. Section 884.5330 is added to subpart F to read as follows:

§ 884.5330 Female condom.

(a) *Identification.* A female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. It is indicated for contraceptive and prophylactic (preventing the transmission of sexually transmitted diseases) purposes.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* No effective date has been established of the requirement



for premarket approval for the devices described in paragraph (b) of this section. See § 884.3 for effective dates of requirement for premarket approval.

Dated: May 9, 2000

Linda S. Kahan,
Deputy Director for
Regulations Policy,
Center for Devices and
Radiological Health.

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